Secretary Leavitt's Response to SACGHS Letter and Relevant Agency Activities
Reed V. Tuckson, M.D. and Relevant Ex Officios

DR. TUCKSON: We're going to begin again. We are now at the section on updating on direct-to-consumer marketing of genetic tests. We identified, as you will recall, direct-to-consumer marketing of genetic tests and services as an important issue.

We had several discussions during our priority setting process about the advertising and sale of dubious genetic tests over the Internet. Examples of ads such as genetic tests for personalized face cream, and even more alarming, for addictive behavior, a slide by the way that Francis Collins shared that I use regularly in my presentations, which never fails to get people's attention on this subject.

We heard from Matthew Daynard about the role of the FTC -- that's the Federal Trade Commission -- in regulating false and misleading advertisements, and their need for documentation of harm before they can pursue advertisers. Some of the areas touched upon during committee discussions include how spurious claims may drive the consumers to waste precious health care resources, or delay the introduction of valid therapies.

There is no gate keeper guarding patients from the dangers unique to genetic technology. Genetics is a field that already confuses much of the public. Direct-to-consumer marketing may create more confusion and could be a serious roadblock to progress.

In December of 2004, we sent a letter to the Secretary that first expressed our concern about potential harm to consumers from direct-to-consumer marketing of genetic tests and services. Second, that requested clarification on the role of FDA in monitoring such marketing, and third, that recommended that HHS collect data on the public health impact of DTC marketing, and collaborate with the Federal Trade Commission on the monitoring of such advertising.

In March, we received a response from Secretary Leavitt, and you can find that in Tab 5 of your briefing book. Since that time, there have been some efforts to address our concerns. During an interagency conference call on this topic in April, two working groups were established to respond to our recommendations. We will be hearing updates on those working groups shortly.

Following the working group updates, Deborah Wolf from FDA's Center for Devices and Radiological Health Office of Compliance is with us, and we're happy that she is able to provide an update on FDA's role in monitoring the marketing of genetic tests and services.

Before we hear Deborah's formal presentation, I'd like to ask Matt Daynard from the FTC and Deborah Wolf from FDA to update us on collaborative efforts within the federal government to monitor such advertising.

Matt and Deborah, can you give us that update, please?

MR. DAYNARD: Thank you, yes. Matt Daynard.

I'm happy to report that the FDA/FTC/NIH DTC Advertising Task Force is up and running and working well, due largely to the wonderful efforts of Steve Gutman and Deborah Wolf sitting next to me, and Fay Shamanski of NIH.

What they have done is put together a wonderful chart that has potential targets. On the left side there are claims, somewhere in the middle, a synopsis of the science supporting those claims of potential consequences, both health-wise and economic.

They presented that to me, and we had a telephone conference about that. I commented on those in terms of what was good, what more we needed. What the FTC needs in this area since the lawsuit here, if this is what we're looking at down the road, would be an entirely new application of the FTC Act. We need the proverbial slam dunk.

We don't want any scientific issues that anybody on the other side could debate. So this is what we're looking at. The FDA and NIH are going back and doing a little bit more work, for which I'm eternally grateful. They're going to come back to me after this committee meeting, sometime in the very near future, and we'll discuss it again.

When we have a consensus on good targets, I'm going to take that to my folks in the Division of Advertising Practices and the Bureau of Consumer Protection and say listen, I have told you about this, you have been a bit excited, we wanted to see what we'd come up with. Here are the potential targets. Hopefully I'll be able to say this is a good case. If they agree, we will take this to the Bureau of Consumer Protection folks and get their heads up sort of agreement, and we'll take it from there.

You have to realize that unlike the FDA, our hook is not the public health, although that's an enormous criteria in our case selection. Our hook is advertising. We've got to find a strong claim, which is not supported by competent or reliable scientific evidence, and then we take it either to court or to an administrative law judge.

Part of that of course scenario is well, what is the potential public health consequence? What's the economic consequence? How strong is the claim? What is the science?

What we're looking at are claims that some of these tests can help you lose weight over the long term, or can help you determine whether you're susceptible to serious diseases like cancer, or that they can prescribe a nutritional diet for you in the future that in fact will help you avoid some of these diseases or avoid obesity. FDA in particular is checking into the science on these, and how the tests are performed. That does make a difference as to how predictable they are and projectable they are.

So they are doing all this work. It is quite wonderful, and I think we are off to a great start.

DR. TUCKSON: Matt, thank you for that.

Let me just ask one quick question here. I mean, given the ones we've seen in terms of this addictive behavior, does your child suffer from the predisposition to alcoholism, drug abuse, or learning disabilities, just send in your swab and we will give you the right nutriceuticals that will, based on this genetic profile, solve the problem.

I mean, there are some pretty interesting examples out there. I guess where I'm sort of struggling with is wondering why you're having such a hard time finding or narrowing down the right test case.

MR. DAYNARD: Because what we're talking about are specific facts. What is the exact claim. What is the science supporting that claim? How serious is the condition that the test that the advertiser purports the claim that the test is going to show you?

Addictive behavior, that affects us all, and we're all concerned about that. But the kind of claims that we deal with on a daily basis are cancer cures, AIDS cures, bogus HIV test kits, which we just did with the FDA. So that's the kind of claim that gets our attention.

DR. TUCKSON: Got it. Well, we'll have a chance to dialogue. By the way, again, I'm glad you're moving forward. One of the things that I must say as we listen to Muin, who is coming next, and then we'll get to the formal presentation, then we have questions after that is apparently observers in prominent scientific publications in commenting on this process have decided to label our activity as a committee on this moving at a glacial pace.

(Laughter.)

DR. TUCKSON: While they are apparently pleased that we're doing things, apparently we are characterized as moving at a glacial pace. Hopefully whatever commentator that is that wrote this will after this meeting decide that maybe we are at least moving at a more aggressive glacial pace, but that we are trying to do this seriously.

Let me also take this opportunity, again, for the new members, to remind you. There are a lot of people that pay attention to what we do. We may not always agree with how they interpret our activity, but we are being interpreted. So be mindful that there is a lot of scrutiny of what we are doing, as it should be, because we exist in the public domain.

Muin from CDC.

DR. KHOURY: Yes. Thank you, Reed, very much.

Actually in that same article I was quoted as saying that my friends at the FDA are doing nothing. So that tells you how your words can be distorted. So my apologies to the FDA if my words said the wrong thing at the wrong time.

Anyway, we had a conference call last week to begin the process of discussion of how HHS is going to respond to kind of collect data on the public health impact on the direct-to-consumer marketing of genetic tests. We have a working group that has a representative from NHGRI, NCI, FDA, Joe Hackett serves on it, and a few folks from CDC. I would welcome any of the new members on this effort. Our work has just gotten started.

I want to thank Sarah and the SACGHS staff for keeping us on target. Our job is not as easy as it seems. Measuring public health impact has multiple facets to it. First you have to define what that means. As I said, we had a brainstorming session.

At the outset, we kind of decided to break into two groups, two types of tests, if you will. The ones that are squarely within the health care delivery systems where you have direct-to-consumer advertisement that is done within the context of health care providers. Examples of this is the BRCA1 analysis campaign a couple of years ago. The other ones are the ones that are outside the system, direct access to that.

It impacts on our ability to how we can measure impact if something is within the health care system, as I mentioned briefly with the public health response to the BRCA1 analysis campaign. Presumably if people do this outside the system, then there is really not too many immediate ways of finding the outcomes or impact of such advertisement.

But we kind of began to kick around a few questions. Obviously the ultimate impact is to find out the outcomes of people who are tested and not tested, whether people are being helped or served by such targeting. I think, as I said, it will be a few steps before we can devise the kind of data collection instruments to get there.

There are a few more I guess what I call process measures that one can use. Consumers knowledge, attitudes, and behaviors. I mean, other people have heard about these things and whether it affected their knowledge or their behavior in seeking them and why they seek them, who are they, and whether or not the outcomes have changed.

So we started that discussion. Let me just give you a quick summary. In your tab I guess there is an example of a public health response to the BRCA1 campaign that happened two years ago, which was in a way a natural experiment. It happened in an intensive way over a six month period in two cities in the U.S., in Denver at Atlanta.

At that time, there were at least two responses that happened. We partnered with health departments in Colorado and Georgia to mount surveys to health care providers and women of the right age group. Random surveys to find out what is going on. There is an MMWR article in your packet, and a peer reviewed publication on its way. At the same time, Kaiser in Colorado did a similar analysis in the Kaiser community. The advantage of using HMOs is that you have numerators and denominators. You have a closed system, although it may not be representative of the population, but you know referral patterns.

The paper in Nature Medicine just appeared in March this year. You guys can peruse it. Both of these surveys showed an impact of such campaigns. I mean, it is a no brainer. Advertisement works. It makes people think, it makes people act. Whether it changes outcomes or appropriateness of referrals, that's something to be looked at.

But during our discussion last week on the phone, we kind of began to think about the ways to essentially tackle the problem. I'd be curious to get some more input from the committee here. One is to partner directly with these companies. We were cautioned to work more with the other subgroup here, because on the one hand, if some other part of the government is pursuing them, I think partnering with them to seek data on who uses their services, and obviously there are privacy concerns and business practices that may not allow us to do this.

But for us, I think finding out why people use these services and what the impact of these services on their own health is what we're after, to try to document these things. So we decided to shelf this for the moment until we figure out what the other group is doing.

We talked about HMO research networks as a good place to do these kinds of activities and surveys. We'll be trying to pursue this. But of course this methodology will miss out of pocket purchases and direct access. In other words, if it doesn't come back to the health care providers and be in the chart, there is no way you can capture the impact of such a practice.
The third methodology is to piggyback on existing surveys that CDC and state health departments do on an ongoing basis. One of the surveys CDC does on a yearly basis is the Health Styles survey, which is a random sample of a representative sample of the U.S. population, about 45,000

people. We are going to be adding Doc Styles this year, which is a random sample of physicians to find out what people do, and what practices look like.

Again, if the magnitude of the issue is small, I mean, 4,000 people may not be enough to pick up if it is only one person in 5,000 that uses these services, it would be very difficult to pick up. But at least establishing baseline rates of different things will be important, and you can track it over time.

Now, of course states have different surveys. One of them is the Behavioral Risk Factor Surveillance System which is a state based survey. We will be looking to partner with several states to evaluate the data collection systems as long as we are able to devise sort of minimum sort of core elements for how we can do this.

So anyway, we are going to be exploring different things over the next few months, adding questions to existing surveys, both state and federal, and working with HMOs. I look forward to working more with different members of this committee and trying to get a better handle on this public health issue.

DR. TUCKSON: Great.

DR. KHOURY: Thank you, Reed.

DR. TUCKSON: All right. Let me just march into the presentation, and I'll come back and we'll do the questions at the end. Is that all right, or do you have something?

DR. McCABE: It's very brief.

DR. TUCKSON: Okay.

DR. McCABE: It is appropriate now. I would suggest that Emma Marris, who wrote the piece that you commented on before for Nature Genetics, that you contact her, Mr. Chairman, about the genetic nondiscrimination, since she seems interested in genetics.

DR. TUCKSON: Good. Thank you for connecting the dots. That's great.